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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,868

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,868	Applicant(s) TREMBLAY ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/19/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment and election with traverse filed 2/19/08 is acknowledged.

Upon reconsideration and due to applicant's amendments, the species election is withdrawn.

Claims 1-6 and 11 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 and 11 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by McGinnis, *Journal of Applied Phycology* **9**: 19–24, 1997. 19

The claims are directed to a method for producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

McGinnis teaches a process of culturing diatomaceous algae wherein at least some of the diatoms where in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., page 20, col. 2, paragraph 2.

Claims 4-5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Dempster TA ((1994) Influence of environmental parameters on growth and lipid production in *Nitzschia communis*. M.S. Thesis, Arizona State University, 100 pp.)

The claims are directed to a method for producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

Dempster teaches a process of culturing diatomaceous algae wherein at least some of the diatoms where in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 33-42.

Claims 1, 3, 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Taguchi *et al.*, of record.

The claims are directed to a method for producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

Taguchi teaches a process of culturing diatomaceous algae wherein at least some of the diatoms where in exponential growth phase when growth limiting factors, such as silicate

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deprivation, were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 33-42.

Claims 1-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over . McGinnis *et al.* taken with Dempster and Taguchi *et al.*

The claims are directed to a method for producing polyunsaturated fatty acids from diatomaceous algae, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids

McGinnis teaches a process of culturing diatomaceous algae wherein at least some of the diatoms where in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., page 20, col. 2, paragraph 2.

Dempster teaches a process of culturing diatomaceous algae wherein at least some of the diatoms are in exponential growth phase when growth limiting factors are applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 33-42.

The references differ from the claimed invention in that silicate deprivation is not disclosed. However Taguchi *et al.* teach the influence of silicate deficiency on lipid synthesis by diatoms. Taguchi *et al.* studied the effects of *Chaetoceros gracilis*, *Hantzschia* and *Cyclotella* strains and shows the favorable effects of lipid accumulation, including, of course, polyunsaturated fatty acids, after exponential growth and growth arrest. See, e.g., Fig 1.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of McGinnis *et al.* and Dempster by culturing diatomaceous algae under various growth-limiting conditions including silicate deprivation, as suggested by the teachings of Taguchi *et al.* for the expected benefit of maximizing the content of lipids in the diatomaceous algae cultures, including polyunsaturated

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fatty acids known to be useful in the pharmaceutical industries as well as being nutritionally essential to organisms such as oysters, fish and shrimp which are important nutrient sources for humans.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
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